II. AMENDMENTS TO THE CLAIMS

Claim 1. (currently amended) A method for lowering blood glucose levels in human patients needing treatment for non-insulin-dependent diabetes mellitus (NIDDM), comprising orally administering to human patients on a once-a-day basis at least one oral controlled release dosage form comprising an effective dose of metformin or a pharmaceutically acceptable salt thereof and an effective amount of a controlled release carrier to control the release of said meformin or pharmaceutically acceptable salt thereof from said dosage form, wherein following oral administration of a single dose, the dosage form provides a mean time to maximum plasma concentration (T_{max}) of metformin at from 5.5 to 7.5 hours after administration following dinner; and the administration of the at least one metformin dosage form provides a mean AUC_{0-24} of 22590 ± 3626 ng·hr/ml and a mean C_{max} of 2435 ± 630 ng/ml on the first day of administration and a mean AUC_{0-24} of 24136 ± 7996 ng·hr/ml and a mean C_{max} of 2288 ± 736 ng/ml on the 14th day of administration, for administration of a 2000 mg once-a-day dose of metformin.

Claims 2-3 (cancelled)

Claim 4. (previously presented) The method of claim 1, in which the administration of the at least one metformin dosage form provides a mean time to maximum plasma concentration (T_{max}) of metformin at from 6.0 to 7.0 hours after administration.

Claim 5. (previously presented) The method of claim 1, in which the administration of the at least one metformin dosage form occurs at dinner time and provides a mean time to maximum plasma concentration (T_{max}) of metformin at from 5.5 to 7.0 hours after the administration.

Claim 6. (cancelled)

Claim 7. (previously presented) The method of claim 1, in which the administration of the at

least one metformin dosage form provides a width at 50% of the height of a mean plasma concentration/time curve of metformin from about 4.5 to about 13 hours.

Claim 8. (previously presented) The method of claim 1, in which the administration of the at least one metformin dosage form provides a width at 50% of the height of a mean plasma concentration/time curve of metformin from about 5.5 to about 10 hours.

Claim 9.(previously presented) The method of claim 1, in which the administration of the at least one metformin dosage form provides a mean maximum plasma concentration (C_{max}) of metformin which is more than about 7 times the mean plasma level of said metformin at about 24 hours after administration.

Claim 10. (previously presented) The method of claim 1, in which the administration of the at least one metformin dosage form provides a mean maximum plasma concentration (C_{max}) of metformin which is from about 7 times to about 14 times the plasma level of said metformin at about 24 hours after administration.

Claim 11. (previously presented) The method of claim 1, in which the administration of the at least one metformin dosage form provides a mean maximum plasma concentration (C_{max}) of metformin which is from about 8 times to about 12 times the plasma level of said metformin at about 24 hours after administration.

Claims 12 - 13. (cancelled)

Claim 14. (previously presented) The method of claim 1, in which the administration of the at least one metformin dosage form provides a mean $AUC_{0\text{-}24hr}$ from at least 80% of the mean $AUC_{0\text{-}24}$ provided by administration of an immediate release reference standard twice a day, wherein the daily dose of the reference standard is substantially equal to the once-a-day dose of metformin administered in the controlled release oral dosage form.

Claim 15. (previously presented) The method of claim 1, in which the administration of the at least one metformin dosage form provides a mean $AUC_{0\text{-}24hr}$ that is from at least 90% of the mean $AUC_{0\text{-}24}$ provided by administration of an immediate release reference standard twice a day, wherein the daily dose of the reference standard is substantially equal to the once-a-day dose of metformin administered in the controlled release oral dosage form.

Claims 16-17. (cancelled)

Claim 18 (currently amended) The method of claim ~~16~~1, in which the once-a-day dosage of the metformin is about 2000 mg, which is provided by two controlled release dosage forms containing about 1000 mg.

Claims 19 - 21. (cancelled)

Claim 22. (previously presented) The method of claim 1, in which the administration of the at least one metformin dosage form provides a mean $AUC_{0\text{-}\infty}$ of 18277 ± 2961 ng·hr/ml and a mean C_{max} of 1929 ± 333 ng/ml, for administration of a 1700 mg once-a-day dose of metformin.

Claims 23 - 25. (cancelled)

Claim 26. (previously presented) The method of claim 1, in which the administration of the at least one metformin dosage form provides a mean $t_{1/2}$ from 2.8 to 4.4.

Claim 27. (previously presented) The method of claim 1, further comprising administering to said human patients at least one additional pharmaceutically active ingredient for treatment of NIDDM.

Claim 28. (previously presented) The method of claim 1, further comprising administering to said human patients an additional pharmaceutically active ingredient for treatment of NIDDM, said additional pharmaceutically active ingredient selected from the group consisting of a sulfonylurea, a glitazone or a second biguanide.

Claim 29. (previously presented) The method of claim 1, in which the dose of metformin comprises metformin hydrochloride.

Claim 30. (original) The method of claim 29, in which the once-a-day dose of metformin hydrochloride is about 1000 mg to about 2500 mg.

Claim 31. (original) The method of claim 29, in which the once-a-day dose of metformin hydrochloride is about 2000 mg to about 2500 mg meformin.

Claims 32-34. (cancelled)

Claim 35. (new) The method of claim 1, in which the once-a-day dose of metformin or pharmaceutically acceptable salt thereof is 2000 mg.

Claim 36. (new) The method of claim 1, in which the once-a-day dose of metformin or pharmaceutically acceptable salt thereof is 1000 mg.

Claim 37. (new) The method of claim 1, in which the once-a-day dose of metformin or pharmaceutically acceptable salt thereof is 500 mg.